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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,268	12/20/2000	Klaus Abraham-Fuchs	P00,1908	7104

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EXAMINER	
FRENEL, VANEL	
ART UNIT	**PAPER NUMBER**
3627	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/742,268	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	Vanel Frenel	3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Pre-Appeal Brief Review filed on 9/28/06. Claims 1-28 are pending.

2. Applicant's arguments filed on 9/28/06 have been persuasive and a new Office Action is hereby presented.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (6,354,299) in view of Kaufman et al (5,868,135).

(A) As per claim 1, Fischell discloses a method for allowing a patient, suffering from a neurological disease and receiving medication for said disease, to self-monitor the patient's actual state (See Fischell, Abstract; Col.6, lines 49-67 to Col.7, line 3), comprising the steps of:

providing a computer at a location readily accessible to a patient substantially on a daily basis for acquiring information from a patient (See Fischell, Col.9, lines 39-61);

acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient (See Fischell, Col.15, lines 57-67 to Col.16, line 6); providing an expert system accessible by the computer (See Fischell, Col.17, lines 10-55);

Fischell does not explicitly disclose that the method having providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication; and

providing said computer with an output device and making said quantified indicator available to the patient via said output device.

However, these features are known in the art, as evidenced by Kaufman. In particular, Kaufman suggests that the method having providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication (See Kaufman, Col.4, lines 26-60); and

providing said computer with an output device and making said quantified indicator available to the patient via said output device (See Kaufman, Fig.4; Col.6, lines 36-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Kaufman within the system of Fischell with the motivation of detecting when the individual should receive predetermined medication (See Kaufman, Col.3, line 10-11).

(B) As per claim 2, Kaufman discloses a method wherein said information comprises information characterizing a motor function of said patient, and wherein the step of conducting an interactive procedure comprises conducting software-controlled motor function exercises for identifying negative and positive effects of said medication on said patient's state, and quantifying said negative and positive effects for processing by said expert system for producing said quantified indicator (See Kaufman, Col.7, lines 1-35).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Kaufman discloses a method wherein said information is information characterizing a verbal communication ability of said patient, and wherein conducting an interactive procedure comprises acoustically acquiring speech from said patient and assessing said speech with a speech assessment system in said computer containing speech recognition algorithms and a phonetic data bank to obtain an information value quantifying negative and positive effects of said medication on said speech, and supplying said information value to said expert system for processing by

said expert system for producing said quantified indicator (See Kaufman, Col.4, lines 23-60).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Fischell discloses a method wherein said information is information characterizing cognitive abilities of the patient, and wherein conducting an interactive procedure comprises generating questions by said computer and requiring a response from said patient to the respective questions and, from said responses, generating an information value quantifying negative and positive effects of said medication on said cognitive abilities of the patient, and supplying said information value to said expert system for processing in said expert system to produce said quantified indicator (See Fischell, Col.3, lines40-67).

(E) As per claim 5, Kaufman discloses a method comprising acoustically entering said responses from said patient into said computer (See Kaufman, Fig.4, Col.6, lines 30-60).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(F) As per claim 6, Kaufman discloses a method comprising manually entering said responses from said patient into said computer (See Kaufman, Col.6, lines 30-60).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(G) As per claim 7, Fischell discloses a method comprising entering additional information into said computer in said interactive procedure characterizing a subjective state of health of said patient (See Fischell, Abstract; Col.25, lines 1-31).

(H) As per claim 8, Fischell discloses a method comprising obtaining a quantified information value representing said information in said interactive procedure, and storing, as stored information with respect to time, at least one of said quantified indicator, said information and said quantified information value after each interactive procedure (See Fischell, Col.34, lines 9-53).

(I) As per claim 9, Fischell discloses a method comprising providing said stored information to said expert system, and producing in said expert system an evaluation regarding dosage of said medication based on said stored information and making said evaluation available to the patient at said output device (See Fischell, Col.33, lines 36-67).

(J) As per claim 10, Fischell discloses a method wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation from an analysis of a curve relative to time of the respective quantified

indicators obtained after each interactive procedure (See Fischell, Col.34, lines 9-53).

(K) As per claim 11, Fischell discloses a method further comprising making said chronological curve available to said patient as a displayed curve at said output device (See Fischell, Col.25, lines 1-31).

(L) As per claim 12, Fischell discloses a method comprising storing said evaluation in a memory accessible by said computer (See Fischell, Col.18, lines 24-38).

(M) As per claim 13, Fischell discloses a method comprising establishing communication between said computer and a physician located remote from said computer, and informing said physician of at least one of said quantified indicator and said evaluation and said information, as transmitted information (See Fischell, Col.32, lines 55-67 to Col.33, line 35).

(N) As per claim 14, Fischell discloses a method comprising transmitting therapy instructions from said physician to said computer based on an examination of said transmitted information, and making said therapy instructions available to the patient at said output device (See Fischell, Col.33, lines 36-67 to Col.34, line 26).

(O) As per claim 15, Fischell discloses a method comprising formulating said quantified indicator as a number (See Fischell, Col.20, lines 37-49).

(P) As per claim 16, Fischell discloses a method comprising formulating said quantified indicator as a statement (See Fischell, Col.20, lines 50-67 to Col.21, line 22).

(Q) As per claim 17, Fischell discloses a system for allowing a patient suffering from a neurological disease and receiving medication for treating said disease, to self-monitor a state of the patient, comprising: a computer readily accessible by the patient

disposed at a location at which said patient is present substantially on a daily basis (See Fischell, Col.9, lines 39-61);

at least one software program installed in said computer for operating said computer to execute an interactive procedure with said patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing verbal communication abilities of the patient, and information characterizing cognitive abilities of the patient (See Fischell, Col.15, lines 57-67 to Col.16, line 6);

an input unit connected to said computer for use by said patient during said interactive procedure for acquiring said information (See Fischell, Col.9, lines 39-61);.

Fischell does not explicitly disclose that the system having an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer; and

an output unit connected to said computer for providing said quantified indicator to the patient.

However, these features are known in the art, as evidenced by Kaufman. In particular, Kaufman suggests that the system having an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer (See Kaufman, Col.4, lines 26-60);

and

an output unit connected to said computer for providing said quantified indicator to the patient (See Kaufman, Fig.4; Col.6, lines 36-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Kaufman within the system of Fischell with the motivation of detecting when the individual should receive predetermined medication (See Kaufman, Col.3, line 10-11).

(R) As per claim 18, Fischell discloses a system wherein said information is information characterizing a motor function of the patient, and wherein said input unit is a manually operated input unit, and wherein said software program operates said computer to execute motor function test exercises and produces a quantified information value quantifying negative and positive effects of said medication on said motor function and makes said quantified information value available to said expert system (See Fischell, Col.21, line 19-67).

(S) As per claim 19, Kaufman discloses a system wherein said information is information characterizing verbal communication abilities of the patient, and wherein said input unit is an acoustical input unit, and wherein said software program assesses speech made by said patient into said input unit using speech algorithms and a phonetic data bank, and produces a quantified information value representing said verbal communication abilities, and makes said quantified information value available to said expert system (See Kaufman, Fig.112; Col.6, lines 61-67).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claims 1 and 17, and incorporated herein.

(T) As per claim 20, Kaufman discloses a system wherein said information is information characterizing cognitive abilities of the patient and wherein said software operates said computer to present questions to said patient and to receive responses from said patient, and produces a quantified information value from said responses quantifying negative and positive effects of said medication on said cognitive abilities, and makes said quantified information value available to said expert system (See Kaufman, Col.5, lines 14-45).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claims 1 and 17, and incorporated herein.

(U) As per claim 21, Fischell discloses a system comprising a further software program for operating said computer to obtain additional information from said patient characterizing a subjective state of health of said patient (See, Fischell Col.1, lines 19-57 Col.3, lines 5-39).

(V) As per claim 22, Fischell discloses a system wherein said software program in information, and further comprising a memory accessible by said computer and by said expert system for storing, as stored information relative to time, at least one of said quantified indicator, said information and said quantified information value after each interactive procedure (See Fischell, Col.36, lines 31-67).

(W) As per claim 23, Fischell discloses a system wherein said expert system produces an evaluation from said stored information with regard to a dosage of said medication (See Fischell, Col.15, lines 43-67).

(X) As per claim 24, Fischell discloses a system wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation by analyzing a chronological curve of respective quantified indicators obtained from successive interactive procedures (See Fischell, Fig.8, Col.21, lines 35-67).

(Y) As per claim 25, Fischell discloses a system wherein said computer displays

said chronological curve as a displayed curve at said output device (See Fischell, Fig.8; Col.21, lines 35-67; Col.25, lines 1-31).

(Z) As per claim 26, Fischell discloses a system further comprising a transmission link from said computer to an external computer located remotely from said computer for transmitting at least one of said evaluation and said quantified indicator to said external computer (See Fischell, Col.26, lines 8-40).

(AA) As per claim 27, Fischell discloses a system wherein said software operates said computer to formulate said quantified indicator as a number (See Fischell, Fig.8; Col.21, lines 35-67 to Col.22, line 18).

(BB) As per claim 28, Fischell discloses a system wherein said software operates said computer to formulate said quantified indicator as a statement (See Fischell, Col.21, lines 35-67 to Col.22, line 18).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not the applied art teaches modular microprocessor-based health monitoring system (5,899,855) and apparatuses and methods for automatically assessing and monitoring a patient's responsiveness (2003/0145854).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 571-272-6769. The examiner can normally be reached on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zeender Florian can be reached on 571-272-6790. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

V.F
V.F

December 22, 2006

Andrew Joseph Rudy
Primary Examiner, AU 3627